United States District Court
District of Massachusetts

Gianna Krstic,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	**Civil Action No.**
Sofregen Medical Inc., et al.,	)	**18-11585-NMG**
	)	
Defendants.	)	
	)	
	)	

MEMORANDUM & ORDER

GORTON, J.

Plaintiff Gianna Krstic ("Krstic" or "plaintiff") brings this products liability action against defendants Allergan, Inc. ("Allergan") and Sofregen Medical Inc. ("Sofregen") (collectively "defendants"). She alleges that the SERI Surgical Scaffold ("the SERI") which was implanted during her bilateral breast reconstruction surgery was defective due to defendants' negligent design, manufacture and marketing of the SERI medical device. She asserts that, as a result, she suffered significant injuries, anxiety, depression and wage loss.

Pending before this Court are defendants' motions to dismiss, in part, the third amended complaint for failure to state a claim. For the reasons that follow, those motions will be denied.

I. Background

Defendant Allergan is a Delaware corporation with its principal place of business in Irvine, California and was the manufacturer of the SERI at the time of plaintiff's surgery. Defendant Sofregen is a Delaware company with its principal place of business in Cambridge, Massachusetts and is the purported successor-in-interest of Allergan with respect to the SERI product. Plaintiff is a resident of North Carolina and was domiciled in Florida during the time of the relevant surgical procedures giving rise to this action. She sues in this Court based on diversity jurisdiction.

In July, 2014, plaintiff underwent bilateral reconstruction surgery during which her plastic surgeon, a paid Allergan consultant, implanted the SERI into plaintiff's breasts apparently without her knowledge. Thereafter, plaintiff contends that she began experiencing chest pain, right arm pain, swelling and immobilization and infections at the surgery site. She asserts that she eventually became "incapacitated in her normal lifestyle".

After multiple consultations with and evaluations by physicians, it was determined that the pain was due to problems with the SERI. The device had purportedly malfunctioned and hardened inside plaintiff's breast which caused her soft tissue to scar over internally. As a result, in September, 2015,

plaintiff underwent corrective surgery, after which her condition improved temporarily. In November, 2015, however, plaintiff was admitted to the hospital for pericarditis and pleural effusion, conditions she says were caused by the infections. Plaintiff submits that she continues to suffer from pain, anxiety, depression and wage loss.

A. The SERI Device

The SERI is a silk-derived, bioresorbable scaffold which is intended to support and repair soft tissue following surgery. It is designed to reabsorb slowly, rather than harden, into adjacent tissue and, eventually, be entirely reabsorbed. In 2008, the device was supposedly cleared by the United States Food and Drug Administration ("the FDA") for use as an implantable,

> transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome.

Plaintiff submits that the FDA clearance did not include use in breast plastic and reconstructive surgeries but when Allergan acquired the SERI in 2010, it began marketing it as safe for such use, including the kind of breast reconstructive surgery plaintiff underwent. In so marketing the device, plaintiff contends that Allergan did not warn plastic surgeons

or their patients that the device may harden in the body when used in such a manner and cause injuries and complications.

In February, 2015, Krstic asserts that interim data for a clinical trial studying the SERI reported that the device caused several serious side effects and complications in patients whose physicians used it in breast reconstruction surgeries. Plaintiff submits that, consequently, in May, 2015, the FDA issued a letter to Allergan warning that it had been improperly marketing the SERI without clearance or approval by the FDA for "off-label marketing", in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h).

In or about November, 2016, Allergan apparently sold its rights in the SERI to Sofregen. Since acquiring the SERI, plaintiff contends that Sofregen has continued to market and sell the SERI for off-label uses, in the same manner that Allergan had done.

B. Procedural History

In July, 2018, plaintiff filed her original complaint in this Court against defendants Allergan and Sofregen. Several months later, she filed her first amended complaint, whereupon Sofregen filed a motion to dismiss for failure to state a claim. As of April, 2019, that motion remained unopposed (by mistake of plaintiff's counsel) and this Court allowed it and dismissed the action. Plaintiff promptly filed a motion to vacate the

dismissal and for leave to file a second amended complaint, both of which this Court ultimately allowed, thereby reopening the case.

In July, 2020, Krstic filed, with leave of the Court, her third amended complaint. That complaint alleges two counts: negligence (Count I) and fraudulent concealment (Count II). The negligence claim includes allegations of defective design and manufacture and a failure to warn. Her fraudulent concealment claim is also based on a failure to warn.

With respect to the warning-based claims, plaintiff contends that defendants failed to warn plastic surgeons and their patients of the dangers and risks associated with "off-label" use of the SERI, including that the device may harden inside of the soft tissue when used during breast reconstruction surgery. She adds, inter alia, that, had such a warning been provided to her plastic surgeon, the surgeon

> could have made an educated decision of whether or not to even use the [SERI] in this manner.

In August, 2020, defendant Allergan filed a motion to dismiss Count I of the third amended complaint to the extent it is based on an alleged failure to warn of the risks associated with the SERI and Count II in its entirety based on a lack of causation. In January, 2021, defendant Sofregen filed its

motion to dismiss, in part, the third amended complaint for the same reasons identified by Allergan.

II. Motions to Dismiss

A. Legal Standard

To survive a motion under Fed. R. Civ. P. 12(b)(6), the subject pleading must contain sufficient factual matter to state a claim for relief that is actionable as a matter of law and "plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable for the misconduct alleged. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011).

When rendering that determination, a court may not look beyond the facts alleged in the complaint, documents incorporated by reference therein and facts susceptible to judicial notice. Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011). A court also may not disregard properly pled factual allegations even if actual proof of those facts is improbable. Ocasio-Hernandez, 640 F.3d at 12. Rather, the relevant inquiry focuses on the reasonableness of the inference of liability that the plaintiff is asking the court to draw. Id. at 13.

A claim sounding in fraud must also comply with Fed. R. Civ. P. 9(b) which requires a party to state "with particularity the circumstances constituting fraud". Fed. R. Civ. P. 9(b). To meet those requirements, a plaintiff

> must specify the time, place, and content of an alleged false representation sufficiently to put defendants on notice and enable them to prepare meaningful responses.

OrbusNeich Med. Co. v. Boston Sci. Corp., 694 F. Supp. 2d 106, 118 (D. Mass. 2010). That standard is satisfied when a plaintiff avers with particularity the "who, what, where and when of the allegedly false or fraudulent representation" but other elements, such as intent and knowledge may be pled in general terms. Rodi v. S. New England Sch. Of Law, 389 F.3d 5, 15 (1st Cir. 2004).

B. Application

The parties agree that Florida law governs plaintiff's substantive claims.

i. Failure to Warn

Defendants move this Court to dismiss Count I of the third amended complaint to the extent it asserts a failure to warn of the risks associated with the SERI and Count II in its entirety based on the "learned intermediary doctrine". They assert that both counts ultimately allege a failure to warn by defendants as to which plaintiff has failed plausibly to allege causation. Defendants contend specifically that, to state her warning-based

claims, Krstic is required to allege that her plastic surgeon would have acted differently had the surgeon received an adequate warning from Allergan but that plaintiff failed to so allege.

Under Florida law, a manufacturer of a dangerous product has a duty to provide adequate warnings of the known risks associated with that product. Dimieri v. Medicis Pharms. Corp., No. 14-cv-176, 2014 WL 3417364, at *3 (M.D. Fla. July 14, 2014). For medical products, that duty is directed toward the treating physician, rather than his or her patients, because the physician is deemed to be a "learned intermediary" who is able to

> weigh[ ] the potential benefits against the dangers in deciding whether to recommend the [medical device] to meet the patient's need [("the learned intermediary doctrine")].

Felix v. Hoffman-LaRoche, Inc., 540 So.2d 102, 105 (Fla. 1989); see also Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1367–38 (S.D. Fla. 2007) (applying the learned intermediary doctrine to medical devices).

The learned intermediary doctrine applies to all causes of action which are based on a medical device manufacturer's alleged failure to warn, including those sounding in negligence and fraud. See Beale, 492 F. Supp. 3d at 1372. To succeed on warning-based claims, a plaintiff must establish, inter alia, proximate cause, namely, that the manufacturer's failure to

provide adequate warnings to the learned intermediary proximately caused plaintiff's injuries. See Eghnayem v. Boston Sci. Corp., 873 F.3d 1304, 1321 (11th Cir. 2017) ("Under Florida law, to succeed on a failure to warn claim a plaintiff must show (1) that the product warning was inadequate; (2) that the inadequacy proximately caused her injury; and (3) that she in fact suffered an injury from using the product.").

To establish proximate cause, therefore, a plaintiff must show, "that her treating physician would not have used the product had adequate warnings been provided". Id. At the pleading stage, such a showing requires the plaintiff to allege that her treating physician lacked

> substantially the same information as the manufacturer due to [(1)] inadequate warnings and/or [(2)] a lack of independent knowledge.

Dimieri, No. 14-cv-176, 2014 WL 3417364, at *3; see also Felix, 540 So.2d at 105 (finding a lack of causation because "the prescribing physician testified that he fully understood the warnings and also had prior knowledge of the [drug's risks]"); Baker v. Danek Med., 35 F. Supp. 2d 875, 881–82 (N.D. Fla. 1998) (finding a lack of causation because the treating physician "was fully aware of all the risks and benefits of implant[ing] the defendant's device").

This Court finds that the warning-based claims in the third amended complaint are not barred by the learned intermediary

doctrine because Krstic alleges that 1) Allergan failed to warn her plastic surgeon of the risks associated with the SERI, 2) the surgeon lacked independent knowledge of such risks and 3) plaintiff suffered significant injuries as a result of its implantation.

Specifically, plaintiff states that her treating physician received no warning that the SERI was more likely to malfunction and harden when used during breast reconstruction surgeries. She also contends, with respect to the surgeon's independent knowledge, that,

> [h]ad defendants alerted [plaintiff's plastic surgeon] to these medical problems caused by off-label use, [the surgeon] could have made an educated decision of whether or not to even use the Product in this manner.

That allegation permits the reasonable inference that Krstic's plastic surgeon lacked independent knowledge of the risks associated with the SERI because, if she had such knowledge, she could have made an educated decision without the warnings. Cf., Baker, 35 F. Supp. 2d at 881–82 (finding a lack of causation because the treating physician "was fully aware of all the risks and benefits of implant[ing] the defendant's device").

Furthermore, defendants have not rebutted plaintiff's allegation that her plastic surgeon neither received adequate warning nor had independent knowledge of the risks associated with the SERI. Defendants are correct that the third amended

complaint does not explicitly state that plaintiff's surgeon would have changed her decision to use the SERI had she been adequately forewarned. Nonetheless, Krstic alleges that the surgeon was unaware that the SERI could harden when used during breast reconstruction surgery and thus a reasonable inference can be made that adequate warnings would have altered her decision and prevented plaintiff's injuries. Accordingly, because plaintiff plausibly alleges proximate cause and defendants' motions to dismiss depend entirely on her purported failure to do so, their motions will be denied.

ORDER

For the foregoing reasons, defendants' motions to dismiss, in part, the third amended complaint (Docket Nos. 70 & 88) are **DENIED**.

So ordered.

\s\ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated February 3, 2021